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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,561	03/19/2002	Jerry M Collins	31978-178825	6698
26694	7590	08/06/2004	EXAMINER	
VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP			JONES, DAMERON LEVEST	
P.O. BOX 34385			ART UNIT	
WASHINGTON, DC 20043-9998			PAPER NUMBER	

1616

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/088,561

**Applicant(s)**

COLLINS ET AL.

**Examiner**

D. L. Jones

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 42-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7, 20-31 and 41-49 is/are allowed.
- 6) ☒ Claim(s) 8-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                        |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

Art Unit: 1616

## ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 5/24/04 wherein claims 1, 3-5, 7, 8, 12, 13, 19, 20, 41, and 41-49 were amended and claims 32-30 were canceled.

**Note:** Claims 1-31 and 41-49 are pending.

## NEW GROUNDS OF REJECTIONS

### **112 Rejections**

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 8-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8-12: The claims as written are ambiguous because it is unclear what modulators Applicant is referring to in the phrase 'modulators of cellular accumulation mechanisms' (claim 8, lines 1-2) and 'modulator' (claim 8, line 4; claim 9, lines 2 and 3). In addition, in independent claim 8, it is unclear what cellular accumulation mechanisms Applicant is referring to. Furthermore, what 'efflux mechanism' (claim 10) and 'influx mechanism' is Applicant referring to? Thus, since independent claim 8 and some of its dependent claims are ambiguous, claims 9-12 which dependent upon independent claim 8 are ambiguous.

Art Unit: 1616

Claim 13-19: The claims are ambiguous because independent claim 13 is not clear. Did Applicant intend to insert 'at least one of' before 'said' (line 7) and replace 'drug' with 'drugs' (line 7)? It needs to be clear that one of the labeled anti-tumor drugs administered to the subject is an insoluble taxane.

#### **ALLOWABLE CLAIMS**

4. Claims 1-7, 20-31, and 41-49 are allowable over the prior art of record for reasons of record in Applicant's response and the office action mailed 2/24/04.

#### **COMMENTS/NOTES**


5. It should be noted that no prior art has been cited against Applicant's claims. However, while claims 8-19 are allowable over the prior art of record for reasons of record, Applicant must address and overcome the 112 rejections above.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
D. L. Jones  
Primary Examiner  
Art Unit 1616

August 5, 2004